The opinion in support of the decision being entered today was <u>not</u> written for publication and is not binding precedent of the Board

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN WALLACE PARCE, ANNE R. KOPF-SILL and LUC J. BOUSSE

Application No. 2004-2342 Application No. 09/721,508

HEARD: APRIL 21, 2005

Before ELLIS, SCHEINER and GRIMES, <u>Administrative</u> <u>Patent Judges</u>.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal pursuant to 35 U.S.C. § 134 from the examiner's final rejection of claims 78, 81 and 87. Claims 1-74 and 91-107 have been canceled. The examiner has indicated that claims 75-77, 79, 80, 82-86 and 88-90 are allowable. See Office Action mailed February 12, 2003, p. 5.

As a preliminary matter, we note the appellants' statement on page 4 of the main Brief that the claims stand or fall together. Accordingly, we will consider the issues as they apply to claim 78 which is representative of the subject matter on appeal. Claim 78, and claim 76 from which it depends, read as follows:

- 76. An apparatus for conducting a microfluidic process, said apparatus comprising:
 - (a) a first plate comprising an array of sample access ports adapted for receiving a plurality of samples from an array of sample wells; and
 - (b) a second plate integral with said first plate, said second plate comprising a planar array of microfluidic networks of cavity structures and channels for conducting a microfluidic process wherein each of said microfluidic networks is adapted for fluid communication with a corresponding sample access port of said first plate.
- 78. The apparatus of claim 76, wherein said array of sample wells conforms to the format of a 96, 192, 384, or 1536 well plate.

The examiner does not rely on any references in his rejection of the claims.

Claims 78, 81 and 87 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed.

We have carefully considered the respective positions of both the appellants and the examiner and find ourselves in substantial agreement with that of the examiner. Accordingly, we affirm.

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Background and Discussion

As indicated by the claims above, the present invention is directed to a multiwell apparatus for testing a "plurality of samples." According to the appellants, said invention is "useful for performing high throughput screening assays. In particular, . . . [it] provides microfluidic devices that are useful in screening large numbers of different compounds for their effects on a variety of chemical, and preferably, biochemical systems." Brief, p. 2.

The examiner argues that the specification, as originally filed, does not provide an adequate written description of the claimed invention. Answer, pp. 3-4. The examiner points out that the claims were copied from U.S. Patent No. 6,103,199, in order to provoke an interference. <u>Id.</u>, p. 2. The examiner acknowledges that the specification describes an apparatus for testing compounds which has multiple wells; however, he contends that the specification does not provide written descriptive support for sample wells that conform to a format of a 96, 192, 384 or 1536 well plate. <u>Id.</u>, p. 4.

In response, the appellants argue that

the present invention provides microfluidic devices that are useful in screening large numbers of different compounds for their effects on a variety of chemical, and preferably, biochemical systems. Specification, page 7, lines 5-9. The specification notes that in the interest of efficiency, screening assays have typically been set up in multi-well reaction plates, e.g., multi-well microplates, which allow for the simultaneous, parallel screening of large numbers of test compounds. Specification, page 10, lines 29-32. The microfluidic assay chips (704) of the present invention include a plurality of interfaces (708), e.g., pipettors, that lower into the array of sample wells of a plurality of multi-well

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microplates (711)(emphasis added). Specification, p. 36, lines 1-14; FIG. 7 [Brief, p. 7].

Thus, the appellants contend that because the specification discloses multi-well microplates that are used to screen large numbers of compounds, it [the specification] "satisfies the written description requirement for a <u>multi-well</u> microplate." <u>Id.</u>, p. 8.

With respect to the number of sample wells recited in representative claim 78, the appellants argue that the specification does not need to describe exactly the claimed subject matter in order to satisfy the written description requirement; it need only convey with reasonable clarity that the inventors were in possession of the invention. Brief, p. 8. The appellants further argue that "information which is well known in the art at the time the invention was made need not be described in detail in the specification." Id. The appellants contend that the multi-well format set forth in representative claim 78 was known in the art at the critical time. Id. The appellants rely on several patents for support. Id., pp. 8-9.

We find these arguments unpersuasive.

This application is said to be a continuation, pursuant to 35 U.S.C. § 120, of Application No. 09/346,660, filed July 1, 1999, now U. S. Patent No. 6,558,944, which is a continuation of Application No. 08/671,987, filed June 28, 1996, now U.S. Patent No. 5,942,443. As such, no new matter can be added to the specification after the filing date. 37 C.F.R. § 1.53(d)(5).

When new matter is added to the claims, the proper course of action is to reject said claims for failing to satisfy the written description requirement of §112, first paragraph. In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981)("The proper basis for rejection of a claim amended to recite elements thought to be without support in the original disclosure, therefore, is § 112, first paragraph ..."). The purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field as far as described in the patent specification." Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000). To that end, to satisfy the written description requirement, the inventor "must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [first emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). "One shows that one is 'in possession' of the invention by describing the invention, with all its claimed limitations . . ." [emphases in original]). Lockwood v. American Airlines, 107 F.3d 1563, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

We point out that it is not necessary for the specification to describe the claimed invention <u>ipsissimis verbis</u>; all that is required is that it <u>reasonably</u> convey to those skilled in the art that, as of the filing date sought, the inventor was in possession of the claimed invention. <u>Union Oil of California v. Atlantic Richfield Co.</u>, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000); <u>Vas-Cath Inc. v. Mahurkar</u>, 935 F.2d at 1563-

- 64, 19 USPQ2d at 1119; In re Gosteli, 872 F.2d 1008,1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989); In re Edwards, 568 F.2d 1349, 1351-52,196 USPQ 465, 467 (CCPA 1978). Here, we agree with the examiner, that the specification does not provide written descriptive support for the number of wells recited in the claims at issue. In reviewing the sections of the specification relied upon by the appellants we find that they discuss multi-well microplates for screening multiple test compounds; however, the number of wells is not delineated. See, the specification, p. 7, lines 5-9; p. 10, lines 29-32; p. 36, lines 1-14; and Figure 7. We find the following described on page 36 of the specification and in Figure 7.
- 1. A multi-well apparatus (test compound processing system (700)) wherein the wells are shown as (711) and are positioned on a conveyor (712). The test compounds are present on plates (714) stacked at one end of the conveyor.
- 2. The plates are stepped down or loaded onto the conveyer where they are exposed to the assay chips (704).
- 3. Each assay chip (704) is said to contain "a number of discrete assay channels 706, each having a separate interface 708, e.g., pipettor, for introducing test compounds into the device [chip]." Specification, p. 36, lines 4-7.
- 4. The interfaces (708) "are used to sip test compounds into the device [chip]." Specification, p. 36, lines 7-8.
- 5. "[T]he interfaces of the chip are inserted through an opening 710 in the bottom of the platform 702, which is capable of being raised and lowered to place the interfaces

in contact with test compounds or wash/spacer/guard band fluids, which are contained in the multiple wells (711). Specification, p. 36, lines 9-15.

6. The plates containing the test compounds are collected and stacked at the opposite end of the conveyer (722).

It is not possible to discern from the apparatus shown in Figure 7 how many wells (711) for screening the test compounds are present. From the number of openings (710) on the platform (702), it appears that, at best, the device in the figure has ten (10) wells. We find no mention in the specification as to the use of more than ten (10) wells to screen large numbers of compounds. To the contrary, it reasonably appears from the description of the invention set forth in the specification and Figure 7, that one skilled in the art would understand that to assay additional test compounds one would simply increase the number of plates (containing said compounds), rather than increase the number of wells. Thus, given the written description of the invention in the specification, which includes the manner in which it operates, we do not find that it [said description] reasonably conveys to those skilled in the art that the appellants were in possession of an apparatus having a "96, 192, 384 or 1536 well plate" as set forth in representative claim 78.

Nor are we persuaded by the appellants' arguments that information which was known and available in the art, "need not be described in detail in the specification."

Brief, p. 8. We point out that "[t]he written description requirement is not satisfied by what could have been described, but was not." Enzo Biochem Inc. v. Gen-Probe Inc.,

285 F.3d 1013, 1022, 62 USPQ2d 1289, 1295 (Fed. Cir. 2002); Lockwood v. American Airlines, 107 F.3d at 1572, 41 USPQ2d at 1966 (the description requirement is not met by combining the actual disclosure with knowledge in the art). It is the specification which must describe the invention in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought. Lockwood, supra citing to Martin v. Mayer, 823 F.2d 500, 504, 3 USPOQ2d 1333, 1337 (Fed. Cir. 1987)(stating that it is "not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure ... Rather, it is a question whether the application necessarily discloses that particular device"). In any event, we note that most of the patents relied upon by the appellants to support their position issued after the filing date of the present application. That is, we point out that the effective filing date of the present application is June 28, 1996. Thus, even if we assume, arguendo, that the appellants are correct that they need not describe what was known in the art at the time the application was filed, we would not find that those patents which issued after June 28, 1996, reflect that knowledge.

Moreover, if we assume, <u>arguendo</u>, that the specification need not describe that which is well known in the art, we still would not find that the prior art relied upon by the appellants, in combination with the teachings in the specification, demonstrate that they were in possession of the claimed invention. Here, we do not find the multiwell plates described in the prior art patents to be analogous to appellants' invention. That is to say, the multiwell plates of the prior art do not function in the same manner as in the

invention described in the specification (at page 36 and in Figure 7). As discussed above, the multiwell microplates described in the specification assay test compounds by means of wells (711) on a conveyer (712); test compounds are loaded from a stack on one side (714) and appear to move, in some fashion, across the platform and are subsequently stacked up at the platform's end (722). No additional wells are needed to assay more test compounds, only additional plates. The microtiter plates described in the prior art are stationary wells. Different testing fluids or buffers can be added and siphoned off by mechanical means (usually a pipette). Unlike the present invention, the only way to test additional compounds using the prior art microtiter plates was by using more wells. Thus, because the prior art microtiter plates are functionally different from the multiwell microplate described in the specification, we do not find, and the appellants have not explained, how they can be combined with the apparatus described in the specification to provide written descriptive support for an apparatus having a "96, 192, 384 or 1536 well plate" as set forth in representative claim 78.

We find the appellants' reliance on Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986) cert. denied, 480 US 947 (1987), to support their arguments with respect to information known in the art "need not be described in detail in the specification" and the level of skill in the art, to be misplaced. Brief, p. 8. In Hybritech, the issue was enablement. We point out that to date, the Courts have held that the written description requirement is separate and distinct from the enablement requirement of 35 U.S.C. § 112, first paragraph. Festo Corp v.

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Shoketsu Kinzoku Kogyo Kabushiki, 535 U.S. 772, 736, 62 USPQ2d 1705, 1707 (2002); University of Rochester v. G.D. Searle, 358 F.3d 916, 920-921, 69 USPQ2d 1886, 1890 (Fed. Cir. 2004); Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1612 (Fed. Cir. 2002). Here, the issue is written description and the criteria for satisfying this requirement differ from enablement. University of Rochester v. G.D. Searle, 358 F.3d at 920-21, 69 USPQ2d at 1890; Enzo Biochem Inc. v. Gen-Probe Inc., 296 F.3d at 1324, 63 USPQ2d at 1612; Vas-Cath Inc. v. Mahurkar, 935 F.2d at 1563, 19 USPQ2d at 1116. "An invention can be described without an enabling disclosure of how to make and use it . . . [and] 'it is possible for a specification to enable the practice of an invention as broadly it is claimed, and still not describe that invention." University of Rochester v. G.D. Searle, 358 F.3d at 921, 69 USPQ2d at 1891.

Accordingly, in view of the foregoing, the rejection is affirmed.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

JOAN ELLIS

Administrative Patent Judge

Elles

TONI R. SCHEINER

Administrative Patent Judge

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INTERFERENCES

BOARD OF PATENT

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